K072132
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LDR spine A Passion for Innovation

510(k) Summary
LDR Spine ROI-T System

AUG 30 2007

1. **Owner's Name & Address**

LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, TX 78759

Phone: (512) 344-3333
Fax: (512) 344-3350

2. **Contact Person**

James Burrows
Director of Clinical Marketing
LDR Spine USA
4030 West Braker Lane, Suite 360
Austin, TX 78759

Phone: (512) 344-3307
Fax: (512) 344-3350
Email: jamesburrows@ldrspine.com

3. **Date 510(k) Summary Prepared**: July 30, 2007

4. **Trade Name:** LDR Spine ROI-T System
Common Name: Spinal Partial Vertebral Body Replacement Device
Classification: MQP: Spinal Intervertebral Body Fixation
Orthosis - Class II per 888.3060

5. **Legally Marketed Equivalent Predicate Device:**

LDR Spine ROI System (K043349)

6. Device Description

The ROI-T implants are crescent shaped blocks in a variety of heights and lordosis angles. The shape of the ROI-T allows for a larger implant (length and width) to be used.

The ROI-T implants are provided in both an open and enclosed graft design. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants.

7. Intended Use of the Device

The ROI-T is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The ROI-T may be implanted singularly or in pairs. Supplemental internal fixation is required to properly utilize this system.

8. Non-Clinical Performance Data

Mechanical test results demonstrate that the proposed ROI-T System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LDR Spine USA, Incorporated
c/o Mr. James Burrows
Director of Clinical Marketing
4030 West Braker Lane, Suite 360
Austin, Texas 78759

AUG 3 0 2007

Re: K072132
Trade/Device Name: LDR Spine ROI-T System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: August 1, 2007
Received: August 2, 2007

Dear Mr. Burrows:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

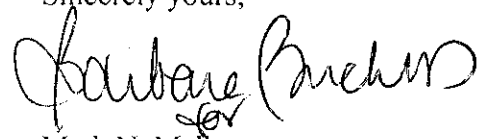
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

K072132

510(k) Number (if known):

Device Name: LDR Spine ROI-T System

Indications for Use:

The ROI-T System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a partial vertebral body replacement in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation. The ROI-T may be implanted singularly or in pairs. Supplemental internal fixation is required to properly utilize this system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072132